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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,309	10/11/2005	Vahe S. Yacoubian	225799-500	1130

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INSKEEP INTELLECTUAL PROPERTY GROUP, INC
2281 W. 190TH STREET
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TORRANCE, CA 90504

EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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03/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

inskeepstaff@inskeeplaw.com

Office Action Summary	Application No. 10/534,309	Applicant(s) YACOUBIAN, VAHE S.	
	Examiner Kennedy J. Schaetzle	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12, 18-20, 26, 29, 30 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12, 18-20, 26, 29, 30, 36, 37 and 39 is/are rejected.
- 7) ☒ Claim(s) 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 9-12, 18-20, 26, 29 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Attachment of the surgical pledget to the myocardium is impermissible because the human body is non-statutory. It is suggested that the applicant recite that the pledget is *adapted to be* fastened to a myocardium to avoid claiming non-statutory subject matter.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Wijk et al. (Pat. No. 6,330,481).

Regarding claim 9, Van Wijk et al. disclose an arrangement for stimulating a heart, comprising in combination: a surgical pledget 33 for being secured to the heart; and a heartwire 30 comprising a wire having a proximal end and a distal end, at least part of the distal end being conductive so as to be usable in heart stimulation (see col.

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7, lines 1-13), and having an end structure comprising an irregular or three-dimensional, atraumatic structure (see half sinus portion 21 of Fig. 3) adapted for engaging said surgical pledget when secured to the heart, for maintaining said heartwire in position relative to said surgical pledget and thereby relative to the heart.

The surgical pledget is adapted to be fastened to the myocardium of the heart by a suture at a first end of said pledget and a second end of said pledget by virtue of suture areas disposed on ends of the pledget (see col. 7, lines 24-40). Claim 9's recitation concerning attachment of the pledget to the myocardium and location of the heart wire between the pledget and the epicardium of the heart, are considered statements of intended use for the apparatus. The pledget of Van Wijk et al. is capable of being sutured and placed as such if one chooses to do so.

The examiner in making the above rejection considers the flat pad element 33 of Van Wijk et al. to be a pledget. Van Wijk et al. disclose that said element may be fashioned from any suitable pliant, biocompatible material such as PTFE or PTFE felt (see col. 7, lines 40-55). The applicant discloses that the pledget of the present invention may be made from TEFLON (PTFE) in par. 0018 of the specification.

Regarding claim 10, the examiner considers the half sinus, single wire embodiment of Fig. 3 to represent a hook.

Regarding claims 11 and 12, as discussed by Van Wijk et al. in col. 5, lines 8-15 and as is old and well-known in the art, the application of electrical therapy to the heart typically requires two leads/electrodes attached to the heart.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 18-20, 26, 29, 30, 36, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Wijk et al. in view of Lowe et al..

Van Wijk et al. do not disclose the use of a chest tube (claim 18) with a groove formed in the peripheral wall (claim 36). The use of chest tubes containing this feature is, however, taught by Lowe et al. to allow for removal of tube apparatus as needed, while leaving sensor structure in the body (see elements 112 of Fig. 10). The general use of chest tubes is taught by Lowe et al. to allow for the collection of valuable diagnostic information following heart surgery. Since both Van Wijk et al. and Lowe et al. are concerned with post surgical apparatus and temporary pacing procedures, and since the particular type of post-surgical treatment and diagnostic data techniques employed have long been recognized to be a matter of physician prerogative dependent upon the condition of the patient, those of ordinary skill in the art would have seen the obviousness of employing the flexible treatment chest tube structure of Lowe et al. in the temporary pacing wire system of Van Wijk et al. Lowe et al. further go on to declare that temporary heart pacing wires (first and second pacing wires are shown in Fig. 17) may be interconnected with the tube as per col. 11, lines 1-21. Elongated structure 110

(Fig. 10) can be removed when no longer required to leave the probe receiving tube and thus the temporary pacing wires in the body (note col. 10, lines 29-38).

Regarding claim 29, the use of anesthesia for surgical procedures of the type required by the practice of the Van Wijk et al. method would necessitate the use of a tube for delivering anesthesia. To therefore incorporate such a tube would have been considered blatantly obvious to relieve patient trauma.

Response to Arguments

7. Applicant's arguments filed November 26, 2008 have been fully considered but they are not persuasive.

Regarding arguments concerning the attachment of the pledget to the myocardium and relative location of the heartwire with respect to the body, statements of intended use in apparatus claims fail to saliently distinguish over apparatus of the prior art that is also capable of such attachment and placement. By analogy, a piece of cloth would be capable of being sewn, glued, stapled, taped, etc., to any number of locations without modification. A cloth that is capable of being sewn on a pair of pants may also be a cloth that is capable of being glued to a shirt. Differences in structure – not intended use—must be relied upon to distinguish one apparatus from another.

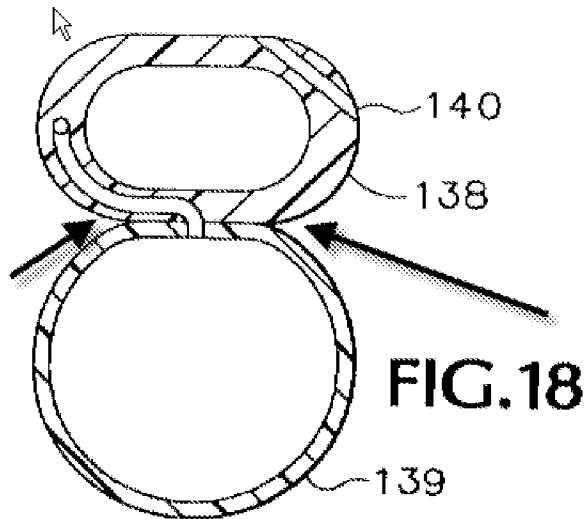
Regarding the argument concerning Van Wijk's use of an adhesive pad, as disclosed in col. 7, lines 24-40, the pad may be directly sutured to the heart. Again, recitations concerning relative location of the pledget to the body will have no effect in overcoming prior art apparatus that is also capable of such positioning. One can also argue that the particular means used to adhere or attach the pledget to the heart would

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have been considered a matter of obvious design by those of ordinary skill in the art.

One would reasonably expect any known surgical means capable of fixing the pledget to the heart to be successful and suitable to the Van Wijk et al. invention.

Regarding claim 36, the examiner considers Fig. 18 to show grooves formed in a peripheral wall of the chest tube as marked by arrow below, with Fig. 17 showing the wires to be placed in at least one of the grooves (i.e., extending longitudinally between a drain tube 138 and an attached probe-receiving tube 139 as per col. 11, lines 1-10).



Regarding claim 39, the applicant states on page 8 of the Remarks that said claim is dependent on claim 18 and is thus allowable for the same reasons that claim 18 is considered to be allowable. Claim 39, however, is an independent claim.

Allowable Subject Matter

8. Claim 38 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information Disclosure Statement

9. Proper identification of the Japanese and Canadian Office Actions is required as per §1.98. The Lowe et al. '514 reference was already considered as indicated in the Office Action mailed May 28, 2008.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
March 10, 2009